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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/557,923	03/10/2006	Gianfranco De Paoli Ambrosi	5759	8082
26/936 7590 12/07/2009 SHOEMAKER AND MATTARE, LTD 10 POST OFFICE ROAD - SUITE 100 SILVER SPRING, MD 20910				
EXAMINER VENKAT, JYOTHSNA A				
ART UNIT		PAPER NUMBER		
1619				
MAIL DATE		DELIVERY MODE		
12/07/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/557,923

**Applicant(s)**DE PAOLI AMBROSI,  
GIANFRANCO**Examiner**

JYOTHSNA A. VENKAT

**Art Unit**

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) 32-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/22/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of election filed on 9/23/09 and IDS filed on 11/22/05. Claims 21-40 are pending in the application. Due to an inadvertent typographical error claims 32-36 are included in group I instead of group II since claims 32-36 includes keratolytic agent and as such group II is drawn to compositions comprising either keratolytic agent and a derivative or prodrug thereof or compositions comprising keratolytic agent, dimethyl isosorbide and derivative or prodrug of keratolytic agent. This error is regretted.

#### ***Election/Restrictions***

Applicant's election of group I in the reply filed on 9/23/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 32-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/23/09.

Applicant election of dimethyl isosorbide and trichloroacetic acid drawn to keratolytic agent in the reply filed on 9/23/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 21-31 are examined to the extent that it reads on the elected species only.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U. S. Patent 5,166,176 ('176) and 5,824,326 ('326) .

### **Claim analysis**

Claim 21 is drawn to composition. Preamble and intended use does not carry any patentable weight as the claims are drawn to compositions and not to method of use.

Patent '176 teaches compositions for healing damaged skin comprising claimed trichloroacetic acid (abstract) and also teaches using surfactants ( also know as emulsifiers belonging to excipients of claims 27- 28). See col.3, ll 5-8 for the amount of trichloroacetic acid which meets the limitation of claim 23 and the amount taught by patent is within the amount claimed in claim 22. Patent at col.3, ll 35 et seq teaches surfactants and at col.4, ll 61-65 teaches glycerin and at col.5, ll 1-10 teaches glycols drawn to claimed solvents (claims 27-28). See also claims of the patent, see claim 20 for water (solvent) and see claims 21-22 for antioxidant and preservatives (claims 27-28 under excipients). The difference between the patent and instant application is patent does not teach dimethyl isosorbide.

Patent '326 teaches cosmetic compositions and teaches claimed dimethyl isosorbide at col.2, ll 57061 and the amount taught by patent is within the amount claimed in the instant application. Patent at col.2, ll 5 et seq teaches various carriers and under claim 1 teaches dimethyl isosorbide.

Accordingly it would be obvious to one of ordinary skill in the art at the time the invention was made to prepare compositions of patent '176 by using trichloroacetic acids,

carriers, and excipients and add dimethyl isosorbide which has also been used in analogous cosmetic compositions. This is prima facie case of obviousness.

Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U. S. Patent 5,166,176 ('176) and 5,824,326 ('326) as applied to claims 21-28 above, and further in view of WO 94/05301 ('301).

The patents cited above do not teach claimed dimethyl sulfone. However WO '301 teaches dermatitis compositions using salicylic acid and dimethyl sulfone. See the abstract. See page 7 under table for MSM , which is same as dimethyl sulfone since dimethyl sulfone is also known as methyl sulfonyl methane. The weight percent is 10% and this is within the weight percent claimed in claim 30 and this weight percent is covered by claim 31.

Accordingly it would be obvious to one of ordinary skill in the art at the time the invention was made to prepare compositions of patent '176 by using trichloroacetic acids, carriers, and excipients and add dimethyl isosorbide which has also been used in analogous cosmetic compositions and add dimethyl sulfone which has been used in skin compositions. This is prima facie case of obviousness.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30:1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, EYLER YVONNE (BONNIE) can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JYOTHSNA A VENKAT /  
Primary Examiner, Art Unit 1619